UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION **Relates to: ALL CASES**	**MDL No. 13-md-2452-AJB(MDD)** **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF EX PARTE MOTION FOR DETERMINATION OF DISCOVERY DISPUTE ON DEFENDANT NOVO'S INTERROGATORY RESPONSES**

This ex parte motion is submitted pursuant to the Court's Civil Chambers Rules regarding discovery disputes. Plaintiffs seek to compel further answers to interrogatories served on Defendant Novo Nordisk Inc. ("Novo"), and to recover their motion costs.

PLAINTIFFS' POSITION

I. INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs served interrogatories on Defendant Novo in November 2013 and January 2014. Defendant first delayed responding, and ultimately provided objections and/or no substantive responses to 26 of the interrogatories, and no meaningful responses to another 22 questions. This pattern of delay and obstruction of discovery has been repeated to varying degrees by each Defendant throughout this case. It must be stopped.

A. Discovery Under The New Schedule

Judge Battaglia has recently ordered that discovery be directed to issues of general causation. *See* Initial Case Management Scheduling Order Regarding General Causation (Dkt. No. 325). Discovery will focus on "whether the requested information has some tendency in logic to prove or disprove whether Defendants' incretin mimetic drugs cause pancreatic cancer." *Id*. The relevance of such information "should not be assessed based on the source of the document, i.e., the Marketing Department, or the category it has been placed in, i.e., Marketing Files, but rather should be assessed based on the 'tendency to make a fact more or less probable than it would be without the evidence.'" *Id*., quoting

Fed. R. Evid. 401(a). In response to Judge Battaglia's Order, Plaintiffs have put a temporary hold on all discovery directed to topics other than general causation.

Parties should always receive timely and complete responses to discovery, but Plaintiffs *must* have that in order to comply with the new schedule.

B. Discovery Background

The Court attended Science Day and is more than familiar with the contours of this litigation. Accordingly, this brief overview is limited to discovery undertaken since formation of the MDL; two agreements reached by the parties that bear on the discovery issues raised in this motion; and the size of Defendants' document productions.

MDL Discovery: When this MDL was formed, plaintiffs combined various pre-MDL discovery sets into several discrete sets of interrogatories and document requests, and served essentially the same discovery on each Defendant.[1] Plaintiffs' first set of interrogatories was served on November 22, 2013; the second set on January 7, 2014, and a trimmed-down "amended" version of the second set on January 30, 2014. Defendant served responses on February 14, 2014, but many consist only of objections, or vague suggestions that substantive responses *may* be forthcoming at some unspecified future date. *See* Ex Parte Motion for Determination of Discovery Dispute, filed herewith.[2]

The Parties' Discovery Agreements: Defendants were concerned that Plaintiffs' written discovery requests might become excessive, and began negotiating with Plaintiffs about limits on written discovery in January 2014. Those negotiations resulted in a proposed joint CMO filed February 18, 2014 (Dkt. No. 320-1), now pending before the Court. Under that agreement, Defendants do not object to any of the interrogatories as

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[1] The only differences in the discovery sets are that drug names were changed to correspond to the drug(s) manufactured by each Defendant, and four additional Byetta-specific document requests were served on Defendants Amylin and Lilly.

[2] This motion is the first of up to eight similar motions (one as to interrogatories for each Defendant, and one as to document requests). Novo was "first up" because it took the lead for Defendants on many of the parties' discovery negotiations. It is hoped that after receiving the Court's guidance, more disputes can be informally resolved.

excessive, but they can still assert other objections. In a contemporaneous second agreement, each Defendant agreed that even if it was "not able to provide a full substantive response" to a request, it would still "respond to the extent it is able." *See* emails between Heidi Levine for Defendants and Mike Johnson for Plaintiffs (**Ex. A**).

Defendants' Document Productions: Defendants frequently refer to the *absolute* size of their document productions, emphasizing the "millions of pages" produced.[3] However, those productions are quite small in relative terms. By no means are the productions even close to the level of "normal" for a drug MDL, much less excessive.[4]

II. THE NEED FOR COMPREHENSIVE DISCOVERY ON GENERAL CAUSATION

Since the start of this MDL, Defendants have repeatedly suggested that just by giving Plaintiffs the IND/NDA data submitted to the FDA, Plaintiffs should have almost everything they need to analyze this case.[5] From Defendants' perspective, the question seems to be a simple one: "If it's good enough for the FDA, why isn't it good enough for you?" It is important that the Court understand the answer to that question.

Extraordinary Incentives: Discovery must reach well beyond the FDA because the "all or nothing" business model of the pharmaceutical industry gives drug manufacturers enormous financial incentives to tell the FDA whatever it wants to hear in order to get a drug approved. Unlike a poorly-made car that can – even despite its poor quality – be sold, a new drug cannot be marketed if it is not approved by the FDA.[6]

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[3] Transcript of Feb. 18, 2014 Status Conference **(Ex. B):** 5:17-24; 7:23-8:1; 40:23-24.

[4] For instance, at least 33 million pages have been produced by Takeda in the Actos litigation (Actos is another Type 2 diabetes medication). *See In re Actos*, 2014 WL 355995, n.58 (W.D. La. Jan. 30, 2014). Over two million *documents* were produced by Merck in the Vioxx litigation, where documents averaged about 15 pages in length, for roughly 30 million pages. *See In re Vioxx*, 501 F.Supp.2d 789, 791 (E.D. La. 2007).

[5] *See*, *e.g.*, **Ex. B:** 5:1-16 (IND/NDA files contain data from numerous clinical trials, FDA communications, etc); 7:23-8:3 (same). Plaintiffs ask that the Court also consider Defendants' pronouncements on this subject on Science Day.

[6] In light of the incentives, it is not surprising that data is falsified, misrepresented and/or withheld from the FDA. Those issues were recently addressed by an FDA investigator

Proven Track Record: The incentives referred to above are not just part of an academic behavioral theory. Rather, drug makers have a clear track record of acting on them. For instance, Defendants in this MDL have paid millions – even billions – to resolve claims of fraudulent marketing.[7] Merck has faced criminal charges.[8] Novo, Merck and Lilly are all under Corporate Integrity Agreements.[9] All of this simply reinforces that it is unrealistic to expect every answer to be found in the cherry-picked and carefully manicured data that drug manufacturers choose to share with the FDA.

The reality is that most drug MDLs do not turn on what was *given* to the FDA, but on what was either *not* given to the FDA, or was misrepresented or obscured. Already, Plaintiffs have found concrete evidence that pancreatic cancer victims were excluded from clinical trials. *See* **Ex. B:** 24:18-25:8. They need to be able to develop "the rest of the story," and can only do so with broad discovery on general causation.

III. LEGAL STANDARDS

Parties may obtain discovery regarding any nonprivileged matter that is "relevant to any party's claim or defense[.]" Fed. R. Civ. P. 26(b)(1). Relevant information includes any information "reasonably calculated to lead to the discovery of admissible

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who described the FDA's clinical trial system as "broken" in an article featured in the British Medical Journal. *See* BMJ 2013;347f6980 **(Ex. C)**. The point here, however, is that information provided to the FDA is only a *starting point* in discovery, not the end.

[7] *See, e.g.,* "Danish Pharmceutical Novo Nordisk to Pay $25 Million to Resolve Allegations of Off-Label Promotion of Novoseven," June 10, 2011, available at http://www.justice.gov/opa/pr/2011/June/11-civ-764.html (cached); "Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa," available at http://www.justice.gov/opa/pr/2009/January/09-civ-038.

[8] "U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx," available at http://www.justice.gov/opa/pr/2012/April/12-civ-497 (Merck made "inaccurate … or misleading statements about Vioxx's cardiovascular safety … to increase sales of the drug.").

[9] Corporate Integrity Agreements (CIAs) are part of a manufacturer's civil settlement with the federal government. CIAs outline the obligations the manufacturer has to meet

evidence," but the information itself does not have to be admissible. *Id*. Any matter that "bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case" is relevant. *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978). Interrogatories may relate to "any matter that may be inquired into under Rule 26(b)." Fed. R. Civ. P. 33(a)(2). Objections must be stated with specificity, and the questions must be answered "separately and fully in writing under oath." *Id*. at 33(b). "The party who resists discovery has the burden to show that discovery should not be allowed, and has the burden of clarifying, explaining, and supporting its objections." *Oakes v. Halvorsen Marine Ltd.*, 179 F.R.D. 281, 283 (C.D. Cal. 1998).

A. Defendant's General Objections

Novo asserted more than three pages of "General Objections" to Plaintiffs' interrogatories. The objections are incorporated into every response, but Novo has not explained what information (if any) it limited or withheld because of the objections.[10] Such objections are not proper and should be disregarded. *See, e.g., U.S. ex rel. O'Connell v. Chapman University*, 245 F.R.D. 646, 649-50 (C.D. Cal. 2007).

B. Defendant's Duty to Perform Reasonable Searches

Novo has said it cannot respond to Plaintiffs' discovery because it is such a large company that any search for responsive information might not gather all of it. *See* **Ex. G**, p. 4. A company's size does not matter, as it should have appropriate discovery procedures in place. *Meeks v. Parsons*, 2009 WL 3003718 at *4 (E.D. Cal. 2009). Regardless, "a reasonable effort to respond must be made." *Haney v. Saldana*, 2010 WL 3341939 (E.D. Cal. Aug 24, 2010). Novo also suggested that since certain information is electronically stored, that may somehow relieve it of its obligation to perform reasonable searches. That again is incorrect: "The producing party should determine the best and

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to continue to participate in certain federal health care programs. *See* Novo's CIA **(Ex. D)**; Merck's CIA **(Ex. E)**; Lilly's CIA **(Ex. F)**.

[10] *See* letter of February 27, 2014 from Mike Johnson to Heidi Levine, p. 3**(Ex. G)**.

most reasonable way to locate and produce relevant information in discovery." Sedona Principles Addressing Electronic Document Production, at Comment 6.a.

C. Science Bias and Influence, and the EMA

Plaintiff's Set 1 Interrogatories seek information on issues of science bias and influence. The questions ask, *inter alia*, about Defendant's interactions with the EMA and scientific journals. Novo objected to all the questions on various grounds, including that the activities of the EMA were "irrelevant." This subject was discussed at some length during the Status Conference on February 18, 2014, when Judge Battaglia learned that Defendants were attempting to erect a "shield" to block discovery on matters – such as the EMA – they had tried to use as a "sword" on Science Day. *See, e.g.,* **Ex. B:** 17:3-16; 33:5-34:13; 38:16-40:3. These interrogatories are key to Plaintiffs' ability to show whether Novo has actively sought to manipulate the science, or to silence any voices raising concerns about the chemical action of these drugs and the ever-increasing cancer rates associated with them.

D. Discovery from Outside the United States

Defendant has objected to certain discovery of matters outside the U.S. However, there is no question that the chemical mechanism of the drugs is the same inside the U.S. as out; that the key adverse events of pancreatitis and pancreatic cancer are the same; that any warnings targeting those issues will be relevant even if not identical to those in the U.S.; and that actions and oversight by foreign regulatory bodies on those issues will be relevant even if not identical to their U.S. counterparts. Given the global ramifications of this issue, overseas discovery on incretin-based therapies should be permitted. *See, e.g., In re Toyota Motor Corp. Securities Litig.*, 2012 WL 3791716 at *16 (C.D. Cal. 2012). Novo's objections to foreign discovery should be disregarded.

E. No Extensions were Requested or Granted

A number of Defendant's non-responses refer to a February 3, 2014 "agreement" that allegedly gave it the unilateral right to delay its answers or not answer questions at all. Plaintiffs understand this to be a reference to the email string attached as **Ex. A**, but

the terms of that agreement expressly required that Defendants "request an extension." None have done so (including Novo), and no extensions have been granted. Plaintiffs have since reminded defense counsel that there no outstanding extensions. *See* **Ex. H.**

IV. SANCTIONS

Interrogatories served months ago have largely been met only with objections. Defendant is stonewalling on discovery while simultaneously pushing for an early discovery cutoff. That is untenable. In addition to getting complete, verified answers to their interrogatories, Plaintiffs request an award of their fees and costs incurred in having to bring this motion, pursuant to Fed. R. Civ. P. 37(a)(3)(B)(iii) and 37(a)(4).

DEFENDANT'S POSITION

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